K041286

JUL 21 2004

X. Summary of Safety and Effectiveness

DynaCAD V1.0

Company:
MRI Devices Corporation
1515 Paramount Drive
Waukesha, WI 53186

Contact:
Thomas Tynes
Manager, Interventional Business Group
Phone: 262-524-1402, Ext. 129
Fax: 262-524-1403
Email: tom.tynes@mridevices.com

Date Prepared:
17 June 2004

Name of Device
Trade Name: DynaCAD™ V1.0
Classification Name: 90 LLZ

Predicate Devices
Vital Images, Vitrea 2 (K002519)
Voxar Limited, Voxar Plug n' View 3D (K992654)
AccuImage, Inc., AccuImage Display Software (K961023)
Mirada Solutions Ltd, Fusion 7D (K020546)
Siemens Medical Solutions, Siemens BOLD MRI (K984221)
GE Medical Systems, GE Advantage Windows With FuncTool Option (K960265)
Philips Medical Systems, Philips EasyVision (Quantitative Analysis Option) (K971965)
Confirma, Inc., Accent (K013574)
Confirma, Inc., CADstream Version 2.0 MRI Image Processing Software (K031779)
3TP, LLC, 3TP Software Option Image Processing Software for MR Devices (K031350)
MRI Devices Corporation, Breast Biopsy Coil (K032576)
MRI Devices Corporation, MR Biopsy (K010570)

Intended Use
DynaCAD is a post-processing software package intended for use in viewing and analyzing magnetic resonance imaging (MRI) studies. DynaCAD V1.0 supports evaluation of dynamic MR data acquired during contrast administration. DynaCAD automatically registers serial patient image acquisitions to minimize the impact of patient motion, segments and labels tissue types based on enhancement characteristics (parametric image maps), and performs other user-defined post-processing functions (image subtractions, multiplanar reformats, maximum intensity projections). The resulting information can be displayed in a variety of formats, including a parametric image overlaid onto the source image. DynaCAD is designed to provide a reliable means of visualizing the presence and pattern of contrast induced enhancements of MRI data sets. DynaCAD also provides an intervention planning tool (DynaLOC) which assists with MRI guidance of percutaneous interventional procedures.

When interpreted by a skilled physician, this device provides information that may be useful in screening, diagnosis, intervention planning and monitoring. DynaCAD can also be used to provide accurate measurements of the diameters, areas, volumes and uptake characteristics of segmented tissues. Patient management decisions should not be made based solely on the results of DynaCAD analysis.

Device Description
DynaCAD image analysis relies on the assumption that pixels having similar MRI signal intensities represent similar tissues. The DynaCAD software simultaneously analyzes the pixel signal intensities from multiple MRI sequences and applies parametric fitting methods to perform tissue segmentation and classification.

The DynaCAD system consists of proprietary software developed by MRI Devices Corporation which is installed on an off-the-shelf personal computer and a monitor configured as a DynaCAD display station.

Software Development
The DynaCAD device has been designed, developed, tested and validated according to written procedures. These procedures identify functions within the organization responsible for developing and approving product specification, coding and testing, verification and validation testing, and technical support.

Performance
The product has successfully completed the required integration and verification testing. Conformance to the DICOM standard has been achieved. Assessment of the product has been performed throughout the design development process in accordance with internal procedures and IEC 601-1-4. Risk management was performed in accordance with ISO 14971.

Clinical Evaluation
Performance testing of the features described in the user manual has been successfully completed utilizing clinical datasets. Software beta testing also has been completed, validating that the requirements for these features have been met. Target accuracy was verified for the DynaLOC package in a clinical setting, using a realistic patient care procedure and placing needles in a phantom.

Substantial Equivalence
The intended use, design, and function and performance characteristics for DynaCAD are substantially equivalent to the predicate devices, particularly those from Confirma and 3TP for image analysis and from MRI Devices Corporation for MR guided breast intervention planning. It is the opinion of MRI Devices Corporation, Inc. that DynaCAD raises no new issues of safety and effectiveness as compared to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 1 200

Mr. Thomas E. Tynes
Manager, International MRI
Business Group
MRI Devices Corporation, Inc.
1515 Paramount Drive
WAUKESHA WI 53186

Re: K041286
Trade/Device Name: DynaCAD V1.0
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH and LLZ
Dated: June 17, 2004
Received: June 18, 2004

Dear Mr. Tynes:

This letter corrects our substantially equivalent letter of July 21, 2004.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120 (see http://www.fda.gov/cdrh/organiz.html#OC for OC organization structure). Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

David A. Lyman

for Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K041286

Statement of Indications for Use

510(k) Number (if known):

Device Name: DynaCAD V1.0

Indications for Use:

DynaCAD is a post-processing software package intended for use in viewing and analyzing magnetic resonance imaging (MRI) studies. DynaCAD supports evaluation of dynamic MR data acquired during contrast administration. DynaCAD automatically registers serial patient image acquisitions to minimize the impact of patient motion, segments and labels tissue types based on enhancement characteristics (parametric image maps), and performs other user-defined post-processing functions such as image subtractions, multiplanar reformats, and maximum intensity projections. The resulting information can be displayed in a variety of formats, including a parametric image overlaid onto the source image. DynaCAD is designed to provide a reliable means of visualizing the presence and pattern of contrast induced enhancements of MRI data sets. In addition to being a Computer Aided Detection (CAD) system, DynaCAD also provides an intervention planning tool, which assists with MRI guidance of percutaneous interventional procedures.

When interpreted by a skilled physician, this device provides information that may be useful in screening, diagnosis, intervention planning and monitoring. DynaCAD can also be used to provide accurate measurements of the diameters, areas, volumes and uptake characteristics of segmented tissues in any original, registered, analyzed or reformatted image. Patient management decisions should not be made based solely on the results of DynaCAD analysis.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K041286